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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/208, 195 12/09/98 SCHNITZER

J BIDMC98-20

EXAMINER

021005 HM12/0815
HAMILTON BROOK SMITH AND REYNOLDS, P.C.
TWO MILITIA DR
LEXINGTON MA 02421-4799

NOLAN, E

ART UNIT

PAPER NUMBER

1644
DATE MAILED:

20

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|-------------------------------|----------------------------------|
| Application No. 09/208,195 | Applicant(s) Schnitzer et al. |
| Examiner Patrick Nolan | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jun 8, 2001 and Jun 29, 2001
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11-17, 19-22, 24, 25, and 27-30 is/are pending in the application.
- 4a) Of the above, claim(s) 27-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 11-17, 19-22, 24, and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

Art Unit: 1644

Part III DETAILED ACTION

1. Claims 1-9, 11-17, 19-22, 24-25 and 27-30 are pending.
2. Claims 27-30 stand withdrawn from consideration as being directed to a non-elected invention, for reasons set forth in Paper No. 14.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-8-01 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9, 11-17, 19-22 and 24-25 is/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolating caveolae by using antibody which binds oligomerized caveolin in its native state as an oligomeric structural cage surrounding intact caveolae, wherein said monoclonal antibody is CAV or otherwise known as Mab clone 2234, does not reasonably provide enablement for the use of any monoclonal antibody which binds oligomerized caveolin in its native state as an oligomeric structural cage surrounding intact caveolae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicant's own specification discloses working examples describing two other art recognized anti-caveolin antibodies that are not able to bind oligomerized caveolin in its native state as an oligomeric structural cage surrounding intact caveolae, (page 14, lines 9-10, in particular). In addition in the declaration submitted by the Inventor, it was recognized that the state of Art taught "In fact, as discussed in Oh and Schnitzer, several antibodies to caveolin were tested and only CAV had reactivity with caveolin in its native state as an oligomeric structure" (page 4, lines 6-8, in particular). Since the state of the art does not recognize any other antibody besides Applicant's CAV antibody can work to immunoisolate caveolae in the claimed method, and the

Serial Number: 09/208,195

Art Unit: 1644

specification's working example is limited to CAV, it would be unpredictable and require an undue amount of experimentation to practice the full scope of Applicant's claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 11 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scherer et al. (U).

Scherer et al., teaches two monoclonal antibodies which are used to immunoisolate caveolae. Mab 2234, which is Applicant's disclosed CAV antibody is used in immunoprecipitation assays to purify caveolae, wherein said antibody is attached to a solid phase and wherein said sample of interest is a disrupted plasma membrane sample, (cell lysing disrupts the plasma membrane, see Materials and Methods, in particular). Since the Mab is the same as Applicant's it has the same functional properties meeting the claim limitations.

It is noted that it is not clear that claims 3 and 4 are limited to plasma membranes or disrupted plasma membranes. If Applicant amends claims 3 and 4 by inserting the term consists of instead of is, the rejection of claims 3 and 4 will be obviated. The prior art teachings anticipate the claimed invention

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan
Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
August 14, 2001